




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

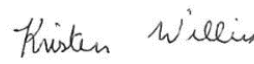
OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: July 10, 2019

Subject: Efficacy Review for CURoxide, EPA Reg. No. 93324-1
(DP Barcode: 451856, E-Submission: 38012)

From: Cesar E. Cordero 
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Chief 
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: July 29, 2019

To: Zeno Bain, Team 33/ Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: CURIS SYSTEM, LLC
1717, Kennedy Point
Oviedo, FL 32765

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hydrogen Peroxide	7.0%
<u>Other Ingredients</u>	93.0%
Total.....	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Ready to use disinfectant fogging solution

Submission type: Amendment

Currently registered efficacy claim(s): Disinfectant: (broad-spectrum) bactericidal: hard, dry, pre-cleaned, non-porous, non-food contact surfaces

Requested action(s): Review efficacy data to amend the label to add a new organism (*Clostridium difficile* (ATCC 43598 - Endospore)) and corresponding use directions for

CURoxide™.

Documents considered in this review:

- Letter from applicant to EPA dated March 29, 2019
 - Revised cover letter received June 4, 2019
- Data Matrix (EPA Form 8570-35) dated March 29, 2019
- 1 efficacy study (MRID 50826301); Statements of No Data Confidentiality Claims, Good Laboratory Practice Compliance Statement, and Quality Assurance Statement were included.
- Proposed label dated (Not dated; reviewed version is attached received June 24, 2019)
 - Revised label (No.1) received June 4, 2019
 - Revised label (No. 2) received June 24, 2019
- Confidential Statement of Formula (EPA Form 8570-4) dated 07/31/2018.
- Efficacy Review for EPA Reg No. 93324-R
 - MRIDs 50526607 and 50526608
- EPA Standard Operating Procedure MB-31-03
- OCSPP 810.2100: Sterilants, Sporicides. And Decontaminants Guidance for Efficacy Testing
- [Guidance for the Efficacy Evaluation of Products with Sporidical Claims Against Clostridium difficile](#) (June 2014)
- [Revised Guidance for the Efficacy of Antimicrobial Products Against Spores of C. difficile on hard, non-porous surfaces](#) (February 2018).

II PROPOSED DIRECTIONS FOR USE

DIRECTIONS FOR USE:

FOGGING

For use as a microbial disinfectant fogging (micron) (misting) solution for disinfection of all dry, pre-cleaned, hard, non-porous, non-food contact surfaces in spaces and rooms. Do not deviate from standard cleaning protocols when using CURoxide™. Use product only with CURIS® System fogging (misting) equipment following detailed instructions provided in the CURIS® User Manual. Read and follow the directions (in the attached package insert) (on the label) on room preparation, room set-up, treatment procedures, and equipment operating procedures for the specific CURIS® System fogging (misting) machine.

This product is for use in CURIS® application equipment only. Read and follow the CURoxide™ (package insert) (label) for complete directions on pre-cleaning, sealing, and use of CURoxide™ in monitored and non-monitored applications. See CURIS® User Manual for operating procedures of the CURIS® System equipment. Do not use this product without development of an appropriate fogging disinfectant plan as described in detail (in the attached package insert) (on the label). Do not deviate from standard cleaning procedures when using CURoxide™ or CURIS® System fogging equipment. CURIS® System micron mist fogging is designed to be the final step in standard cleaning procedures. Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices.

Protect from radiant heat, freezing and direct sunlight. This product is only for use in the CURIS® System CURIS® fogging equipment, and used in accordance with the

CURIS® Fogger Owners Manual. Read and follow the instructions in the CURIS® Fogger Owners Manual for directions on pre-cleaning and preparation of a space. See CURIS® Fogger User Manual for operating procedures. Do not use this product without development of an appropriate fogging disinfectant plan as described in the users manual. Do not deviate from standard cleaning procedures when using CURIS® System. Fogging is designed to be the final step in standard cleaning procedures.

Microbial Disinfection for Fogging

CURoxide™ is a Ready-To-Use product. Do not dilute. Used only on hard, nonporous surfaces. For use as a microbial disinfectant fogging solution for disinfection of dry, pre-cleaned, hard, non-porous, non-food contact surfaces in a space. Do not deviate from standard pre-cleaning protocols when using CURoxide™. Use CURoxide™ only with the CURIS® Fogger following user instructions provided in the CURIS® Fogger Users Manual.

Read and follow the directions on room preparation, room set-up, treatment procedures, and equipment operating procedures. Refer to the CURIS® Fogger Users Manual for complete application instructions. For use in sealed rooms or sealed spaces.

The CURIS® Fogger should be used when (all hard non-porous room surfaces) (the whole room) needs to be disinfected.

Only CURIS® System CURoxide™ products should be used in the CURIS® Fogger. Effective application of CURoxide™ requires adequate product concentration and contact time (FOG and PULSE). The CURIS® Fogger is designed to automatically achieve the correct concentration and contact time of CURoxide™ within a space.

Read the CURIS® System CURIS® Fogger Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.

For use in sealed rooms or spaces in Commercial, Industrial and Institutional settings. The use rate to achieve optimal conditions of >80 ppm hydrogen peroxide, is approximately 0.3 ml of product per cubic feet enclosure or room volume using a FOG time that is auto-calculated depending upon the room size. Once initial fogging phase time has elapsed the Contact time (Pulse Phase) must be maintained for a minimum of 20 minutes before room aeration can begin.

Use a Drager, Portasens, or similar monitor, equipped with a hydrogen peroxide sensor to monitor the minimum effective concentration, as well as re-entry levels within the enclosure are less than or equal to a 1 ppm level (≤ 1.0 PPM TWA 8 hr.) prior to reentry into the enclosure by trained personnel.

The product can be used in enclosures up to 105 m³.

Product Effectively kills the following pathogens:

Staphylococcus aureus (Staphylococcus) (Staph) (ATCC #6538), Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442), Clostridium difficile (spore form) (C.

diff) (ATCC #number 43598)

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores:

- Personal Protection: Refer to label PPE requirements.
- Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection, by application with a clean cloth, mop, and/or sponge saturated with an EPA-registered sporicidal product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed.

Special attention is needed for high-touch surfaces

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

FOOD MANUFACTURING AREAS: In establishments where food and food products are held, prepared, processed and served. Food areas include areas for receiving, storage, packing (boxing, bottling, canning, wrapping), preparing, edible waste storage, enclosed processing systems, serving areas. This product may be used to treat nonfood areas in food handling use sites. Areas include garbage rooms, lavatories, vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, and storage rooms. Treatments with this product may occur only when the facility is not in operation and exposed food is covered or removed from the area being treated prior to treatment. Food contact surfaces must be rinsed with potable water after use of the product.

DIRECT SPRAY DISINFECTION/DEODORIZATION/CLEANING

Read the entire label before using the product. Prior to disinfection, pre-clean surface. For use on hard non-porous, non-food surfaces only. Hold spray bottle **upright 6" to 8"** from surface. Spray 2 to 3 seconds until wet.

To Disinfect*: To disinfect hard, nonporous surfaces, preclean to remove heavy soils. Hold spray bottle **upright 6" to 8"** from surface. Spray 2 to 3 seconds until wet. Let stand. Surface should remain wet for 10 minutes. Let air dry.

To Deodorize: Spray on surfaces as needed. Do not use on polished wood, painted surfaces, leather, rayon fabrics, or acrylic plastics.

Product works by oxidation, not by masking or encapsulating of odors. Eliminates odors caused by fire smoke, tobacco smoke, musty odors, stale-cooking odors, or natural human scent. Simply spray, fog, or wipe on full strength and let air dry to provide long lasting residual deodorizing action. Product must come into contact with the cause of the odor to be effective. For pet urine stains in carpet, blot urine as dry as possible then use full strength to saturate stain with product through carpet pad. Test product for color fastness before using.

Effective disinfectant against the following (10 minute contact time):

*Bacteria:

*Staphylococcus aureus (Staphylococcus) (Staph) (ATCC #6538), Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442)

Pre-cleaning Instructions: Remove gross filth and heavy soil by cleaning. Spray product straight onto soils, scrub and wipe clean with a dry paper towel or cloth.

Cleaning and General Claims:

To Clean [Nonporous] Surfaces -and/or- Floors: Spray soiled area, then wipe clean, - or- For spot cleaning, spray and wipe clean with damp sponge -or- mop or cloth.

SPONGES:

To [prevent] [stop] [control] the growth of odor-causing bacteria [in your] sponge[s], spray sponge [with this product] until saturated and let stand 10 minutes.

Allergen Removal:

To [clean and] reduce specified allergens: [Set trigger to SPRAY.] Spray, [wait 1 minute], and wipe excess. [Rinse.] Allow to air dry. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel.]

Allergens:

- Cockroach matter -or- particles
- Dust mite matter -or- particles
- Pet dander -or- dog and cat dander

“Package Insert or additional label language for CURoxide™” (Attached to the label)

III EFFICACY STUDY SUMMARIES

1.	MRID	50826301	Study Completion Date:	03/18/2019
Study Objective		Disinfectant via Fogging Device (<i>C. difficile</i> spores)		
Testing Lab; Lab Study ID		Microchem Laboratory; Study ID GLP2062; Protocol No. P1931		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Clostridium difficile</i> - ATCC 43598 (Endospore)		
Test Method		Evaluating Hard Surface Room Disinfection via Fogging Device against <i>C. difficile</i> – Test Guideline OCSPP 810.2100 and OCSPP 810.2200		
Application Method		RTU Liquid applied via fogging device		
Test Substance Preparation	Name/ID	CURoxide / EPA Reg. No. 93324-1		
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	011118, 021118R2 and 031118R2		
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A		
Soil load		Tri-part soil (Fetal Bovine Serum, yeast extract and mucine)		

Carrier type, # per lot	21 carriers per lot; Stainless steel slide carriers – 15 mm x 36 mm (304 stainless steel with No. 4 finish) and 1 cm discs (approx. 8 mm thickness)					
Test conditions	Contact time	16 min fogging + 20 min dwell	Temp	23°C +/- 3°C	RH	≤50%
Neutralizer	Lethen Broth, 0.1% Catalase (Efficacy Testing) PBS-T with 0.1% sodium thiosulfate (Spore Qualification)					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	<p>Protocol Amendment:</p> <ol style="list-style-type: none"> The signed protocol P1931 originally stated the following in section X. Calculations: <ul style="list-style-type: none"> CFU/carrier = $\frac{(\text{CFU of } 10^X) + (\text{CFU for } 10^Y) + (\text{CFU for } 10^Z)}{10^X + 10^Y + 10^Z} \times C$ <ul style="list-style-type: none"> Where X, Y, and Z are the appropriate dilutions plated. Where C is the total volume of neutralizer. <p>Due to an inadvertent error in copying the calculation from the original method (EPA Standard Operating Procedure, MB-31-17), the calculation used in the report is updated to the following:</p> <ul style="list-style-type: none"> CFU/carrier = $\frac{(\text{CFU of } 10^X) + (\text{CFU for } 10^Y) + (\text{CFU for } 10^Z)}{(a \times 10^X) + (b \times 10^Y) + (c \times 10^Z)} \times C$ <ul style="list-style-type: none"> Where X, Y, and Z are the appropriate dilutions plated. Where a, b, and c are the volumes filtered from the dilution tubes. Where C is the total volume of neutralizer. <p>Protocol Deviation:</p> <ol style="list-style-type: none"> On Jan 28, 2019, during the conduct of study GLP2062 per protocol P1931, tri-part soil (lot: TRI26MAR20 18A) which was added to the inoculum was not prepared per the protocol. The tri-part soil was labeled as if prepared correctly, however, the preparation was inadvertently not verified prior to its use. The final concentration of each individual ingredient added to the tube containing the test microorganism resulted in the components being twice as concentrated as the protocol and the original method intend. As the study results for GLP 2062 met the success criteria, the challenge of higher soil concentration is determined to not impact the study. <p>After reviewing the protocol amendment and deviation:</p> <ol style="list-style-type: none"> The protocol amendment was found to be acceptable. It corrects the CFU/carrier and is consistent with the current formula as described in EPA SOP MB-31-03. 					

	2. The protocol deviation was found to be acceptable.
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IV STUDY RESULTS

Room Conditions and Device Run Times

01/29/2019 – Lot No. 011118						
Test Organism	Test Substance	Initial Temp. / RH	Total Fogging Time	Total Dwell Time	Total Time Evacuation	Total Treatment Time
<i>C. difficile</i> - ATCC 43598	CURoxide™	20.6 °C / 32.9%	16 min	20 min	130 min	166 min

02/06/2019 – Lot No. 021118R2						
Test Organism	Test Substance	Initial Temp./RH	Total Fogging Time	Total Dwell Time	Total Time Evacuation	Total Treatment Time
<i>C. difficile</i> - ATCC 43598	CURoxide™	24.5 °C / 45.0%	15 min 58 sec.	20 min 2 sec.	109 min	145 min

02/07/2019 – Lot No. 031118R2						
Test Organism	Test Substance	Initial Temp./RH	Total Fogging Time	Total Dwell Time	Total Time Evacuation	Total Treatment Time
<i>C. difficile</i> - ATCC 43598	CURoxide™	22.9 °C / 44.8%	15 min 58 sec.	20 min 15 sec.	151 min	187 min 13 sec

Test Substance Dosage

GLP Number	Test Organism	Test Date	Lot# Test Substance	Volume Delivered to Room (mL)	Volume of Test Room (ft³)	Dosage (mL/ ft³)	Indicator Strip Activated?
GLP2062 MRID 50826301	<i>C. difficile</i> - ATCC 43598 (Endospores)	01/29/19	011118	1060	3682	0.29	Yes (Black)
		02/06/19	021118R2	1070	3682	0.29	Yes (Black)
		02/07/19	031118R2	1060	3682	0.29	Yes (Black)

FOGGING – Bactericidal Efficacy Results

Fogging Disinfectant on Hard, Non-Porous, Non-Food Contact Surfaces in a Room/Space, 20 min contact time, Tri-Part Soil Load						
MRID	Organism	Contact Time	Results			Carrier Population Average Log ₁₀ Density
			Lot. No.	Avg. CFU/carrier (Log ₁₀)	Percent Reduction (Log ₁₀)	
50826301	<i>C. difficile</i> - ATCC 43598 (Endospores)	20 min.	011118	<1.00 x 10 ⁰ (< 0.00 Log)	99.9999% (≥ 6 Log)	6.43
		20 min. and 2 sec.	021118R2	<1.00 x 10 ⁰ (< 0.00 Log)	99.9999% (≥ 6 Log)	6.48
		20 min. and 15 sec.	031118R2	<1.00 x 10 ⁰ (< 0.00 Log)	99.9999% (≥ 6 Log)	6.37

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time*	Soil load	Diluent	Organism(s)	Data support tested conditions?
50826301	Disinfectant	Hard, non-porous surfaces	RTU liquid – Applied using a fogging device	20 minutes 15 seconds (21°C)	Tri-part Soil	N/A	<ul style="list-style-type: none"> • <i>C. difficile</i> - ATCC 43598 (Endospores) 	No*

*See section “**IV Label Comments**” (below)

VI LABEL COMMENTS

Label Dated: Label provided for review not dated (See attached label)

1. The proposed label claims that the product, CURoxide™ (EPA Reg. No. 93324-1), when used as a ready-to-use fogging solution on a CURIS® Fogger at a use rate of ~0.3 ml/ ft³, is an effective room/space disinfectant with bactericidal/sporicidal activity against the following organism on hard, non-porous, non-food contact surfaces in the presence of tri-part soil load for a 20-minute contact time:

- *C. difficile* - ATCC 43598 (Endospores)

*These claims are **not acceptable** as they are not supported by the submitted data. Specifically, the 20-minute contact time is not supported by the data submitted for *P. aeruginosa* or *S. aureus*. *C. difficile* is an “additional organism” to be added to the base disinfection claim. Since the data submitted for the base disinfection claim (data submitted under EPA Efficacy Review for Reg. no. 93324-R) supports a 30-minute contact time, the contact time should be revised to 30 minutes for *C. difficile*. If the claim is revised to 30 minutes contact time, the data are acceptable.

2. The Registrant should make the following changes to the proposed label:

- a. **Throughout the label:**

- i. Capitalize the letter “C” when referring to Clostridium where necessary.
- ii. Revise all claims referring to the product efficacy as being able to kill and/or eliminate 99.9999% of bacteria, *Staphylococcus aureus* or *Pseudomonas aeruginosa*, since the data submitted under EPA Efficacy Review for Reg. No. 93324-R was qualitative and does not support this claim. Log reduction claims based on qualitative data are limited to 99.9% reduction. Thus, these claims should be revised to indicate 99.9%. The 99.9999% can only be used for claims specifically referring to *C. difficile* and should be clearly qualified if/when used. (See claims on pages: 5, 6, 7, 8, 9, 19 and 20).
- iii. Delete the term and any variations of the word decontamination (e.g., decontaminates, decontaminant), when referring/describing the product efficacy, from the label. Use of the terms decontaminant/decontamination is reserved for products with claims for *B. anthracis* per [OCSSPP Guidance 810.2100](#). (See claims on pages: 4, 6, 7 and 9)
- iv. Qualify the word “**eliminates**” with the percentage demonstrated in the submitted efficacy data (e.g., 99.9% for bacteria, *P. aeruginosa*, *S. aureus*) or 99.9999% for *C. difficile*). Alternatively, remove claims to eliminate and/or eliminates. Note, for claims that are qualified with for example, 99.9%, brackets should not be used as the qualifier is not optional.

- b. Pages 1 of 47:

- i. Delete and/or clarify the text between braces/curly brackets (e.g. {Optional Claims} and {End Optional Claims}).
- ii. Revise “EPA Reg. No. 93324-R” to “EPA Reg. No. 93324-1”.

- c. Page 2 of 47:

- i. Remove claims for “micron”. No particle size data was submitted to demonstrate that the particles are in the micron range.

- d. Page 3 of 47:

- i. Revise the statement that reads: “The use rate to achieve optimal conditions of >80 ppm hydrogen peroxide...” by replacing “80” with ≥ 139 ppm to be consistent with the efficacy testing conditions. The lowest hydrogen peroxide

concentrations tested for *C. difficile* was 139 ppm at the initiation of the dwell cycle (See Table 5 on MRID 50826301).

- ii. Revise the product's delivery rate from "0.3 ml of product per cubic feet" to "0.4 ml of product per cubic feet" to reflect the data submitted for the base disinfection claims.
 - iii. Revise the contact time to reflect the corresponding submitted efficacy data. The 20-minute contact time is not supported by the data submitted for *P. aeruginosa* or *S. aureus*. The registrant should revise the contact time to 30 min for all microbes throughout the label.
- e. Page 4 of 47:
- i. Revise the "Special label instructions for Cleaning Prior to Disinfection Against *C. difficile* spores" to exactly match the guidance as follows (<https://www.epa.gov/pesticide-registration/methods-and-guidance-testing-efficacy-antimicrobial-products-against-spores>):
 - 1. Personal Protection: Refer to the product label for appropriate personal protective equipment.
 - 2. Cleaning Procedure: Special attention is needed for high-touch surfaces; cleaning in an appropriate manner and adherence to manufacturer's label instructions for use and contact/dwell times is necessary. Pre-clean surfaces to remove soil and filth. Wipe dry. Thoroughly wet pre-cleaned surface with product. Allow surface to remain wet for [contact time]. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.
 - 3. Infectious Waste Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for disposal of infectious materials.
 - ii. Revise "[Sporicidal]" to "sporicidal disinfectant" or "disinfectant with sporicidal activity". Per the 810.2100 guidance there are criteria for making sporicidal claims.
- f. On page 5 of 47:
- i. Revise the statement that reads: "room treatment time of just over 75 minutes..." to "just over 187 minutes..." which more accurately reflects the testing conditions (e.g., See tables under section "**IV Study Results>Room Conditions and Device Run Times**" under column labeled "**Total Treatment Time**").
- g. Page 6 of 47:
- i. Revise the statement that reads: "room treatment time of just over 75 minutes..." to "just over 187 minutes..." which more accurately reflects the testing conditions (e.g., See tables under section "**IV Study Results>Room Conditions and Device Run Times**" under column labeled "**Total Treatment Time**").
 - ii. Revise the statement "Sensor-driven disinfection" to "Sensor-driven disinfectant application". The current language on the draft label may be misleading as it could be interpreted by the user as if the system "validates" the disinfection process.
 - iii. Remove the claim "Validate with *Geobacillus stearothermophilus*". Alternatively, add instructions for use of *Geobacillus stearothermophilus* as a

- validation tool so it is not misleading to the user. For this option, also capitalize “G” in “geobacillus”.
- iv. Revise the following typographical error in: “Eliminated^d [removes] odors [caused by] [bacteria]” by replacing the “d” at the end of “Eliminated” with an “s”.
 - v. Remove “powerful” from the claim “[powerful] portable technology” as it implies enhanced efficacy.
 - vi. Remove the claim “CURoxide meets EPA standards for healthcare [hospital] disinfectant” as it implies agency endorsement.
- h. Page 7 and 8 of 47:
- i. Delete the following claims:
 1. “The only [AHP system] to pass the tri-part soil load test on c.diff”. The Agency does not have a tri-part soil load test.
 2. “Tripart soil load = Biofilm”. A tripart soil load is not associated with biofilm. The agency has a method to support a claim for biofilm: <https://www.epa.gov/pesticides/methods-and-guidance-testing-efficacy-antimicrobials-against-biofilm-bacteria-hard-non>. This product does not have data to substantiate claims for biofilm.
 3. “Tripart soil load = real world scenarios” The agency does not have standards or information to substantiate this claim.
 4. “Tripart soil load = more challenging testing” The agency does not have standards or information to substantiate this claim.
 5. “Medically Disinfected for Your Health and Safety”. This implies protection from disease. See chapter 12 of the Label Review Manual: <https://www.epa.gov/sites/production/files/2017-10/documents/chap-12-nov-2013.pdf>
- i. Page 8 of 47:
- i. Delete the following duplicate statements under “**Specific Disinfecting Claims**”:
 1. “Kills [eliminates] 99.9999% of bacteria [odors] and deodorizes”
 2. “Kills [eliminates] 99.9999% of Pseudomonas aeruginosa [Pseudomonas] bacteria”
 3. “Kills [eliminates] 99.9999% of Staphylococcus aureus [Staphylococcus] [Staph] bacteria”
- j. Page 9 of 47:
- i. Remove “micron mist technology”
 - ii. Remove “a more challenging test” from the claim “Tested in a Tri-part soil load [a more challenging test]”
- k. Page 11 of 47:
- i. Remove “orthopedics” and “gnotobiotics”. These are not use sites.
 - ii. Revise the “other use sites” so that they are all use sites. For example, “education” is not a use site. Similarly revise the entries on page 12.
- l. Page 13 and 14 of 47:
- i. Qualify the heading “Food Handling Use Sites (includes Storage, Preparation, Processing, and Serving):” with “Non-food contact” or an indicator that leads the reader to the section on page 14 of 47 “**FOOD MANUFACTURING AREAS**”. Alternatively, move the paragraph on page 14 of 47 “FOOD MANUFACTURING AREAS” before the list described under “Food Handling Use Sites”.

- ii. Under the “**FOOD MANUFACTURING AREAS:**” add the word “contact” after “nonfood” in the statement “This product may be used to treat nonfood...”
- m. Page 14 and 15 of 47:
 - i. Replace the words “heavily” and “gross” for “visibly/visible” when used as a descriptor of “soiled” areas and/or “filth”. This descriptor, though still subjective, provides an observable indicator to the user that we believe would provide more consistency in the way the use directions are applied, when compared to heavily/gross and similar descriptors.
- n. Page 16 of 47:
 - i. The entry that reads “non-corrosive” appears to be contrary to the language under the “Precautionary Statements” on page 36 of 47 which begins with DANGER: Corrosive. [...].
- o. Page 19 of 47:
 - i. Remove the term “germ(s)”. For more information on the use of the term “germs” please see: <https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels>.
 - ii. Qualify “Disinfects as it cleans” with “when used according to the directions for use for disinfection.” Similarly qualify any other “Two in one....” Claims.
- p. Page 20 of 47:
 - i. Remove the following duplicate statements under “Specific Disinfecting Claims:”
 - 1. “Kills [eliminates] 99.9999% of Pseudomonas aeruginosa [Pseudomonas] bacteria”
 - 2. “Kills [eliminates] 99.9999% of Staphylococcus aureus [Staphylococcus] [Staph] bacteria” (This statement is repeated twice).
 - ii. Qualify “bacteria” in the entry “Kills pathogenic bacteria”.
 - iii. Remove “micron mist”
- q. Page 21 of 47:
 - i. Define the acronym EMS
- r. Page 22 of 47:
 - i. Remove “orthopedics”
- s. Page 42 of 47:
 - i. Under section “**3.2 Personnel**”, please clarify what would be the appropriate conditions that would require “disinfection validation procedures” to be applied.
- t. Page 43 of 47:
 - i. Under section “**4.1 Area Preparation**”, Delete the word “bio-films” from the statement that reads: “a) Remove any visible gross contamination and bio-films from surfaces and equipment before fogging”.
 - ii. Revise numbering under 4.1 c) Area Inspection, sub bullets should be numbered for consistency.
- u. Page 45 of 47:
 - i. Under section “4.5 Protocol”, bullet e), revise contact time per comment c. ii. (See above).
- v. Page 47 of 47:
 - i. Under section “Re-entry”, sub-section “RELEASING TREATED SEALED ROOM FOR RETURN TO SERVICE”, bullet c):
 - 1. Could not find where in the label “insert” it instructs the user/applicant to turn off the “ventilation system including HVAC”. It may be appropriate to include this under section “4.1 Area Preparation”.

[Language in brackets are notes to reviewer]

(Language in parenthesis are optional and may or may not appear on the final label)

CURoxide™

{Optional Claims}

For Use in Healthcare Facilities

For use as a Healthcare-Hospital Disinfectant

For use as a (Healthcare-Hospital) (Hospital-Healthcare) Disinfectant and (General Use) (Multiple Use) Disinfectant

CURIS® Fogger:

Disinfectant Fogging Solution

Effective Against Bacteria

Effective Against c.diff spores

Kills (99.9999% of) c.diff spores [in a Tri-part soil load]

Sporicidal Disinfectant

†Bactericide:*

*†Staphylococcus aureus (Staphylococcus) (Staph) (ATCC #6538), Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442), Clostridium difficile spores (C. diff) (ATCC #number 43598)

Sprayer:

*Bactericide:

*Staphylococcus aureus (Staphylococcus) (Staph) (ATCC #6538), Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442)

{End Optional Claims}

Active Ingredient:

Hydrogen Peroxide.....7.00%

Inert Ingredients.....93.0%

Total.....100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See (back) (side) (right) (left) panel for additional precautionary statements

Net Contents: (as indicated on container)

EPA Reg. No. 93324-R

EPA Est. No. _____ (See batch code for actual establishment number)

(See (bottom) (side) for Lot No. / Data Code, Product No. Expiration Date)

Questions? Comments? (symbol of telephone)

Call: (1-800-928-8708)

Made in the USA

Distributed by: CURIS® System, LLC, 1717 Kennedy Point, Suite 1001, Oviedo, FL 32765 (or an authorized CURIS® System, LLC distributor (insert name))

(CURIS® is a registered trademark of CURIS® System, LLC.)

(Customer Service) (1-800-928-8708) (www.curissystem.com)

(Visit us at -or- For MSDS information) (Insert company website)

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FOGGING

For use as a microbial disinfectant fogging (micron) (misting) solution for disinfection of all dry, pre-cleaned, hard, non-porous, non-food contact surfaces in spaces and rooms. Do not deviate from standard cleaning protocols when using CURoxide™. Use product only with CURIS® System fogging (misting) equipment following detailed instructions provided in the CURIS® User Manual. Read and follow the directions (in the attached package insert) (on the label) on room preparation, room set-up, treatment procedures, and equipment operating procedures for the specific CURIS® System fogging (misting) machine.

This product is for use in CURIS® application equipment only. Read and follow the CURoxide™ (package insert) (label) for complete directions on pre-cleaning, sealing, and use of CURoxide™ in monitored and non-monitored applications. See CURIS® User Manual for operating procedures of the CURIS® System equipment. Do not use this product without development of an appropriate fogging disinfectant plan as described in detail (in the attached package insert) (on the label). Do not deviate from standard cleaning procedures when using CURoxide™ or CURIS® System fogging equipment. CURIS® System micron mist fogging is designed to be the final step in standard cleaning procedures. Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices.

Protect from radiant heat, freezing and direct sunlight. This product is only for use in the CURIS® System CURIS® fogging equipment, and used in accordance with the CURIS® Fogger Owners Manual. Read and follow the instructions in the CURIS® Fogger Owners Manual for directions on pre-cleaning and preparation of a space. See CURIS® Fogger User Manual for operating procedures. Do not use this product

without development of an appropriate fogging disinfectant plan as described in the users manual. Do not deviate from standard cleaning procedures when using CURIS® System. Fogging is designed to be the final step in standard cleaning procedures.

Microbial Disinfection for Fogging

CURoxide™ is a Ready-To-Use product. Do not dilute. Used only on hard, non-porous surfaces. For use as a microbial disinfectant fogging solution for disinfection of dry, pre-cleaned, hard, non-porous, non-food contact surfaces in a space. Do not deviate from standard pre-cleaning protocols when using CURoxide™. Use CURoxide™ only with the CURIS® Fogger following user instructions provided in the CURIS® Fogger Users Manual.

Read and follow the directions on room preparation, room set-up, treatment procedures, and equipment operating procedures. Refer to the CURIS® Fogger Users Manual for complete application instructions. For use in sealed rooms or sealed spaces.

The CURIS® Fogger should be used when (all hard non-porous room surfaces) (the whole room) needs to be disinfected.

Only CURIS® System CURoxide™ products should be used in the CURIS® Fogger. Effective application of CURoxide™ requires adequate product concentration and contact time (FOG and PULSE). The CURIS® Fogger is designed to automatically achieve the correct concentration and contact time of CURoxide™ within a space.

Read the CURIS® System CURIS® Fogger Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.

For use in sealed rooms or spaces in Commercial, Industrial and Institutional settings. The use rate to achieve optimal conditions of >80 ppm hydrogen peroxide, is approximately 0.40.3 ml of product per cubic feet enclosure or room volume using a FOG time that is auto-calculated depending upon the room size. Once initial fogging phase time has elapsed the Contact time (Pulse Phase) must be maintained for a minimum of 3020 minutes before room aeration can begin.

Use a Drager, Portasens, or similar monitor, equipped with a hydrogen peroxide sensor to monitor the minimum effective concentration, as well as re-entry levels within the enclosure are less than or equal to a 1 ppm level (≤ 1.0 PPM TWA 8 hr.) prior to reentry into the enclosure by trained personnel.

The product can be used in enclosures up to 105 m³.

Product Effectively kills the following pathogens:

Staphylococcus aureus (Staphylococcus) (Staph) (ATCC #6538), Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442), Clostridium difficile (spore form) (C. diff) (ATCC #number 43598)

Special Label Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores:

- Personal Protection: Refer to label PPE requirements.
- Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection, by application with a clean cloth, mop, and/or sponge saturated with an EPA-registered sporicidal product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

FOGGING CLAIMS

Miscellaneous Claims

[Helps] plan your infection prevention regimen

[Economical and] easy to apply

Active ingredient exclusively hydrogen peroxide

[Bactericidal], [Sporicidal]

Bleach [Chlorine] [Bleach and Chlorine] [Alcohol] free formula [technology] [disinfection] [disinfecting] [disinfectant]

Bleach [Chlorine] [Bleach and Chlorine] free formula [disinfection] [disinfecting] [disinfectant]

Bringing hospital disinfection to you

Cloud based data management [system]

CURIS Pulse [the fog's dwell time]

CURIS Pulse = fog dwell time

[Decontaminates hard nonporous surfaces]

Disinfection efficacy against bacteria*

Disinfects hard, non-porous, high touch surfaces

Disinfects hard to reach hard, non-porous surfaces in treated room

Disinfects high touch, hard, non-porous surfaces [in treated room]

Disinfects treated hard, non-porous surfaces on high touch equipment

Don't take our word for it, validate it!

Easily incorporated into [current] cleaning procedures

Easy to transport and can be configured to treat multiple spaces simultaneously

Easy, Effective

Economical, [non-corrosive], and easy to apply

Efficient whole [complete] room treatment time of just over 75 minutes [including application time, contact time, and aeration time] allows for room [disinfection] [and] [turnover] on hard non-porous surfaces
[Allows for] room turnover

For use in CURIS® [fogging] [System] [equipment] [by a trained technician]

For use in CURIS® [System] [room] [fogging equipment] [instruments] [device [s]] [fogger [s]] system[s] Healthcare [Hospital] disinfectant

For use in CURIS® System [Fogger]

For use in room fogging equipment [instruments] [devices[s] [fogger[s] system[s]

Get the job right the first time every time

Go [Goes] above, beyond, under, and around disinfecting sprays and wipes

Great [suitable] for frequent [daily] use

Healthcare [Hospital] disinfectant

Innovative formula

Kills on top, around, and under exposed surfaces

Kill the first time, every time

Kills (99.9999% of) *Bacteria [Staphylococcus Aureus and Pseudomonas aeruginosa]

Kills (99.9999% of) c.diff spores

Kills [Eliminates] Clostridium difficile

Kills (99.9999% of) c.diff in a Tripart soil load

Leaves [room] surfaces disinfected

Leaves no residues [no wiping necessary]

Lightweight, easy to transport, and capable of achieving reliable disinfection

Makes [whole-room] [whole-space] disinfecting easier for hard non-porous surfaces

Micron Mist [Dry] [Fogging]

Micron Misting System

Monitor your treatments while moving on to other tasks

More effective than wiping alone

New [this claim will only be sued for the first six months after commercial introduction]

No [mixing] [or] [dilution] [diluting] [labor] required

No toxic [by products] [residues] left behind

No Wipe, No Rinse, Dry Mist

No Wipe, No rinse

Patented Activated Ionized Hydrogen Peroxide [AIHP] technology

Patented Pulse Technology

Patented Technology

Portable technology

Provides a fully portable application

Pulse [technology]

Quality and consistency is our passion

Ready-to-use [formula] [no mixing required]

Room is safe to enter within minutes following aeration, once hydrogen peroxide is below 1 ppm

Effective whole [complete] room treatment time of just over 75 minutes [including application time, contact time, and aeration time] on hard non-porous surfaces

Scalable technology

Self-contained, allowing for reliable disinfection

Sensor-driven disinfection

Sporicidal disinfectant

Sustainable technology

Touchless disinfection

Validate it and see for yourself

Validate it!

Validate with geobacillus stearothermophilus

When you re-enter the room, you can “smell the clean”

Whole [complete] Room Disinfection [Disinfecting] [Disinfectant] [System] on hard non-porous surfaces

Whole [room] [space] [enclosure] [disinfection] on hard non-porous surfaces

Whole Space Disinfection on hard non-porous surfaces

General Product Performance/Usage Claims

[Disinfectant] [Disinfects] [Daily] [Multi-purpose] [Multi-room] [Multi-surface] Kills pathogenic bacteria*

[Disinfectant] [Disinfects] [Daily] [Multi-action] [Multi-purpose] [Multi-room] [Multi-surface]

[Disinfectant]

[powerful] portable technology

Cloud based surveillance technology

Controls odors caused by [bacteria]

Controls odor causing bacteria

CURoxide™ meets EPA standards for healthcare [hospital] disinfectant

Decontaminates hard non porous surfaces

Deodorizes by killing bacteria that causes odor[s]

Deodorizes by killing odor causing bacteria

Deodorizing by killing odor-causing [bacteria] at their source

Disinfects hard pre-cleaned, non-porous, [non-food] contact surfaces in: [use sites]

Easy to use

Effective [alternative] broad-spectrum surface disinfectant

Effectively eliminates (99.999% of) [pathogens*] [bacteria*] from hard, nonporous surfaces

Effective broad-spectrum surface disinfectant

Effectively eliminates (99.999% of) [pathogens] [bacteria] from hard, non-porous surfaces

Effectively eliminates c.diff in a tripart soil load

Eliminated [removes] odors [caused by] [bacteria]

Eliminates [Removes] odor causing bacteria

For [hospital] [healthcare] [medical] [semi-critical care] [long term care] facilities as a disinfectant
For [hospital] [healthcare] [medical] [semi-critical care] [long-term care] environments
For use in [hospital[s]] [healthcare] [medical] [semi-critical care] [long-term care] environments as a disinfectant

For use as a disinfectant / decontaminant

For use on hard, pre-cleaned, non-porous surfaces located in: [use sites]
Disinfection of all pre-cleaned, hard, non-porous room surfaces
Disinfects pre-cleaned, hard, non-porous room surfaces
Gets rid of odors by killing the [bacteria] [that cause them]
Great [suitable] for whole [complete] room [disinfecting] [disinfection] on hard non-porous surfaces
Helps prevent the build-up of odors by killing odor-causing bacteria [on hard, pre-cleaned, non-porous surfaces]
Helps prevent the build-up of odors by killing odor-causing bacteria [on hard, pre-cleaned, non-porous, non-food contact surfaces]
Intended for use in all [medical], [healthcare], [clinical], [semi-critical care] and [long term care] facilities
Intended for use in all [medical], [healthcare], [semi-critical care], and [long term care] environments
Kills [eliminates] (99.999% of) Pseudomonas aeruginosa [Pseudomonas] bacteria
Kills [eliminates] (99.999% of) Staphylococcus aureus [Staphylococcus] [Staph] bacteria

Medically Disinfected for Your Health and Safety

No harmful residues
No more concerns of material [compatibility] or [liability]
No more peeling or bubbling paint
No more pitted or corroded stainless steel
No silver byproducts
Portable disinfection for almost any space
Reaches surfaces that regular disinfectants can't
Reaches surfaces that regular disinfecting can't

Reaches surfaces eclipsing and shadows don't reach
Reduce[s] risk of cross contamination on treated surfaces
Reduce[s] labor costs
Reduces[s] the risk of cross contamination on treated surfaces associated with using a rag, wipe, or sponge.
Reliable results the first time, every time
Remote and manual operation
Room fogger works to disinfect microorganisms* in even the most hard-to-reach areas
Disinfection efficacy against bacteria
Sensor driven system
Sensors ensure you're treating the space to proper conditions
The only device with work flow management

The only [AHP system] to pass the tri-part soil load test on c.diff

Tripart soil load = Biofilm

Tripart soil load = real world scenarios

Tripart soil load = more challenging testing

Cloud based surveillance technology

Tracks staff, locations, treated areas, targeted pathogens and more

Treats, does not cover up [no residue] [no need to rinse after use] as a disinfectant

Use on hard to read areas [like nooks and crannies]

Use this product in [use sites]

Specific Disinfecting Claims

[Disinfectant] [Disinfecting] fogging [formula] [product] for [whole] [complete] room surface
[disinfection] [disinfecting] on hard non-porous surfaces

[You can] [Use] this product in places that are difficult to [disinfect] [reach] such as
nooks and crannies

An effective disinfectant [formula] [product] for use in healthcare facilities

An effective disinfectant [formula] [product] for use in healthcare facilities for [whole] [complete]
room surface [disinfection] [disinfecting] on hard non-porous surfaces

An effective disinfectant [solution] [formula] [product] for use in [hospitals] [healthcare] [medical]
[semi-critical care] [long term care] facilities

An effective disinfectant [solution] [formula] [product] for use in [hospitals] [healthcare] [medical]
[semi-critical care] [long term care] facilities for whole [complete] room surface disinfection
[disinfecting] on hard non-porous surfaces

An effective disinfectant [solution] [formula] [product] for use in [hospital[s] [healthcare] [medical]
[semi-critical care] [long-term care] environments [facilities]

An effective disinfectant [solution] [formula] [product] for use in [hospital[s] [healthcare] [medical]
[semi-critical care] [long-term care] environments [facilities] for whole [complete] room surface
disinfection [disinfecting] on hard non-porous surfaces

An effective disinfectant [solution] [formula] [product] for use in healthcare facilities

An effective disinfectant [solution] [formula] [product] for use in healthcare facilities for whole
[complete] room surface disinfection [disinfecting] on hard non-porous surfaces

Disinfection of all hard non-porous surfaces in a hospital [patient] room

Effective against bacteria*

EPA registered disinfectant [disinfecting] fogging [solution] [formula] [product] for whole
[complete] room surface disinfection [disinfecting] on hard non-porous surfaces

Kills [eliminates] (99.9999% of) c.diff spores in a tripart soil load

Kills [eliminates] [destroys] (99.9999%) [bacteria*] on hard, non-porous surfaces

Kills [eliminates] (99.9999%) bacteria* [odors] and deodorizes

Kills [eliminates] (99.9999%) bacteria [odors] and deodorizes

Kills [eliminates] (99.9999%) of Pseudomonas aeruginosa [Pseudomonas] bacteria

Kills [eliminates] (99.9999%) of Staphylococcus aureus [Staphylococcus] [Staph] bacteria

Kills [eliminates] (99.9999%) Pseudomonas aeruginosa [Pseudomonas] bacteria

Kills [eliminates] (99.9999%) Staphylococcus aureus [Staphylococcus] [Staph] bacteria

Kills bacteria* on commonly touched on hard non-porous, non-food contact surfaces [in
non-residential public places] [in hotel rooms] [in medical facilities]

Kills {Bacteria}

Kills bacteria* on hard non porous, nonfood contact surfaces in public places

Kills the bacteria* that cause [bad] odors

Micron Mist Technology

On hard, non-porous, non-food contact surfaces, this product kills [eliminates] bacteria

On hard, pre-cleaned, non-porous, non-food contact surfaces this product kills [eliminates] bacteria*

Surface disinfectant

[Tested in a Tri-part soil load \[a more challenging test\]](#)

This product [helps] [aids] in the reduction of cross contamination of bacteria* on hard, pre-cleaned, Non-porous treated surfaces

This product helps fight the spread of bacteria on hard, pre-cleaned, non-porous surfaces

This product reduces the risk of cross contamination of bacteria on hard, pre-cleaned, non-porous treated surfaces

This product reduces the risk of cross contamination of bacteria* on hard, pre-cleaned, non-porous treated surfaces

Use this product in places that are difficult to [disinfect] [reach]

Don't take our word for it, Validate it!

Whole [Complete] [Total] Room Surface Disinfectant on hard non-porous surfaces

Whole Space Disinfection on hard non-porous surfaces

[Whole Space Decontamination](#)

[Whole Space Decontamination System](#)

**Staphylococcus aureus* [*Staphylococcus*] [*Staph*] [ATCC # 6538] and *Pseudomonas aeruginosa* [*Pseudomonas*] [ATCC # 15442]

[Medical Healthcare](#) Use Sites for hard non-porous surfaces:

This product [or product name] is designed specifically as a healthcare [ready-to-use] disinfectant [disinfecting] fogging [solution] [formula] [product] for use in the following settings;

[Including but not limited to:](#)

Ambulances -or- [Emergency Medical]

Transport Vehicles

Ambulatory Surgical Centers (ASC)

Anesthesia Rooms or Areas

[Assisted Living -or- Full Care] Nursing Homes

Carts

CAT Laboratories]

Central Service Areas

Central Supply Rooms -or- Areas
Critical Care Units -or- CCUs

Dialysis Clinics [Facilities]

Doctors' Offices

Donation Centers [blood] [plasma] [semen] [milk] [apheresis]
Emergency Rooms -or- ERs
Exam -or- Examination Room[s]
Eye Surgical Centers
Health Care Settings -or- Facilities
Home Health Care Settings
[Hospital] Kitchens (non-food contact surfaces)
Hospices
Hospitals
Intensive Care Units -or- ICU[s] [areas]
Isolation Areas

Laundry Rooms
Laboratories
Long Term Care Facilities [Clinics] [Facilities]
[Medical] Clinics
Medical Facilities
Medical -or- Physician's -or- Doctor's Offices
Newborn -or- Neonatal [Nurseries] [Intensive Care] Units [NICU]
Nursing Homes
Nursing -or- Nurses' Stations
Operating Rooms or ORs
Ophthalmic Offices
Orthopedics
Out-Patient [Surgical Centers (OPSC)] [Clinics] [Facilities]
Patient Areas
Patient Restrooms
Patient Rooms
[Pediatric] Examination Rooms -or- Areas
Pediatric Intensive Care Units [PICU]
Pharmacies
Physical Therapy Rooms -or- Areas
Physicians' Offices
Psychiatric Facilities
Radiology -or- X-Ray Rooms -or- Areas
Recovery Rooms
Rehabilitation Centers
Respiratory Therapy Rooms -or- Areas
Restrooms
Surgery Rooms -or- Operating Rooms -or- ORs
Tissue Banks
Waiting Rooms -or- Waiting Areas
[Gnotobiotics](#)
[Educational Facilities](#)

Other Use Sites

[Animal Sector](#)
[Armed Forces](#)
[BioSafety labs](#)
[Biotech Sector](#)
[Commercial](#)
[Education](#)
[Research Animal Sector](#)
[University](#)

Veterinary Industry
Entertainment
Government
Historic Buildings
Homeland Defense/Security
Hospitality Sector
Industrial
Institutional
Multifamily housing
Military
Pharmaceutical Sector
Public Transportation
Private Transportation
Recreational
Entertainment and Residential Settings and Assets
Senior Living
Tissue banks
Worship Facilities

Specific Areas of use include:

Airplane
Ambulance
Armed Forces/Military (Aircraft)(Installation) (Vessel) (Vehicle)
Barrier isolator
Biological Decontamination Chamber
Biological Safety Cabinet
Blood Bank
Barrack
Boat
Bowling Alley
Bus
Campground Facility
Church (Temple) (House of worship)
Clean Room
Clinic
College or University Facility
Commercial Building
Correctional Facility
Cruise Ship
Day Care Center
Dorm
Factory
Gnotobiotic chambers
Gymnasium

[Health Club](#)

[Home](#)

[Hospital](#)

[Hotel](#)

[Industrial Facility](#)

[Infirmery](#)

[Indoor Playground](#)

[Institutional Facility](#)

[Isolators](#)

[Laundromat \(Institutional\)](#)

[Locker Room](#)

[Manufacturing Plant \(nonfood\)](#)

[Massage Therapy Facility](#)

[Mobile Home](#)

[Motel](#)

[Nursing Home](#)

[Office \(Medical, Physician's, Commercial, Federal, City, County, Sheriff\)](#)

[Pharmaceutical Manufacturing Facility](#)

[Pharmacy](#)

[Planes](#)

[Police Department](#)

[Public Facilities](#)

[Public Restroom](#)

[Recreational Center](#)

[Rental Facility, Restaurant](#)

[Residential Facility](#)

[Retail Facility](#)

[Recreational Vehicle](#)

[School Bus](#)

[Schools](#)

[Semiconductor Manufacturing](#)

[Shelter](#)

[Sports Arena](#)

[Theaters](#)

[Tissue Bank](#)

[Train](#)

[Veterinary Clinic](#)

[Vivarium](#)

[Wafer Processing and Warehouse](#)

Food Handling Use Sites (includes Storage, Preparation, Processing, and Serving):

[Food Manufacturing Plant, Food Handling Establishments, Food warehouses, Cafeteria, Farmer's Market, Fair Grounds, Food Service Establishment \(Restaurant\) \(Fast food\), Supermarket or Grocery Store](#)

FOOD MANUFACTURING AREAS: In establishments where food and food products are held, prepared, processed and served. Food areas include areas for receiving, storage, packing (boxing, bottling, canning, wrapping), preparing, edible waste storage, enclosed processing systems, serving areas. This product may be used to treat nonfood areas in food handling use sites. Areas include garbage rooms, lavatories, vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, and storage rooms. Treatments with this product may occur only when the facility is not in operation and exposed food is covered or removed from the area being treated prior to treatment. Food contact surfaces must be rinsed with potable water after use of the product.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DIRECT SPRAY DISINFECTION/DEODORIZATION/CLEANING

Read the entire label before using the product. Prior to disinfection, pre-clean surface. For use on hard non-porous, non-food surfaces only. Hold spray bottle **upright 6" to 8"** from surface. Spray 2 to 3 seconds until wet.

To Disinfect*: To disinfect hard, nonporous surfaces, preclean to remove heavy soils. Hold spray bottle **upright 6" to 8"** from surface. Spray 2 to 3 seconds until wet. Let stand. Surface should remain wet for 10 minutes. Let air dry.

To Deodorize: Spray on surfaces as needed. Do not use on polished wood, painted surfaces, leather, rayon fabrics, or acrylic plastics.

Product works by oxidation, not by masking or encapsulating of odors. Eliminates odors caused by fire smoke, tobacco smoke, musty odors, stale-cooking odors, or natural human scent. Simply spray, fog, or wipe on full strength and let air dry to provide long lasting residual deodorizing action. Product must come into contact with the cause of the odor to be effective. For pet urine stains in carpet, blot urine as dry as possible then use full strength to saturate stain with product through carpet pad. Test product for color fastness before using.

Effective disinfectant against the following (10 minute contact time):

***Bacteria:**

***Staphylococcus aureus (Staphylococcus) (Staph) (ATCC #6538), Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442)**

Pre-cleaning Instructions: Remove gross filth and heavy soil by cleaning. Spray product straight onto soils, scrub and wipe clean with a dry paper towel or cloth.

Cleaning and General Claims:

To Clean [Nonporous] Surfaces -and/or- Floors: Spray soiled area, then wipe clean, -or- For spot cleaning, spray and wipe clean with damp sponge -or- mop or cloth.

SPONGES:

To [prevent] [stop] [control] the growth of odor-causing bacteria [in your] sponge[s], spray sponge [with this product] until saturated and let stand 10 minutes.

Cleaning and General Claims:

- | | |
|--|---|
| <ul style="list-style-type: none">• 100% biodegradable• A shining [pure] clean you can see/trust• [Available] [with] convenient sprayer head• Bathrooms, sinks and faucets and floor areas• Brightens• Cleans• Cleans bathroom soils• Cleans blood stains• Cleans everyday messes• Cleans fingerprints• Cleans food stains• Cleans rust• Cleans to a shine• Cleans [up] grease and grime• Cleans away allergens and odor• Clear drying• Compatible with equipment surfaces• [Compatible with -or- Suitable] [for use on] equipment surfaces• Compatible with -or- Suitable -or compatible with equipment surfaces for use on hospital surfaces• Cuts -and/or- removes grease -and/or grime -and/or- sweat | <ul style="list-style-type: none">• Ideal for use in gyms -and/or- health clubs -and/or- wellness centers -and/or- fitness centers -and/or- rehab facilities• Cleans beyond the surface• For a deep clean• Get a true clean (with) (this product)• Okay (suitable) to use daily (Okay) (suitable) for weekly use (Okay) (suitable) for monthly use (Okay) (suitable) for regular use (Okay) for everyday use• Ideal for use in schools -and/or- daycare -and/or- universities -and/or- colleges -and/or- offices• Ideal for use on high touch surfaces• Just spray[,] [and] wipe [and you're done]• Labor saving no-rinse formula• Makes cleaning easier• Multi surface cleaner• No added [perfumes] [and] [or] [dyes] [and] [or] fragrance• No fragrance added• Fresh Scent• Clean Scent• No harsh chemical fumes -or- smell -or odor -and/or- build-up -and/or- residue• No rinsing |
|--|---|

<ul style="list-style-type: none"> • Cuts cleaning time • Designed -or- Ideal for daily [cleaning] [use] • Easy [cleaning] • Effective [cleaner -or- cleaning] [formula] • Fecal matter • For a cleaner, fresher household • For direct [spray] application • For easy cleaning • For terminal cleaning • Good for use with microfiber cloths • Great for Kitchen[s] -and/or- bathroom[s] [too] • Smell of clean • Will not harm most hard, nonporous surfaces • Will not harm natural stones [Granite, Marble, Travertine] • Fast & effective cleaning (for pet accidents) • For a cleaner, fresher household • Effectively (removes) (eliminates) tough (dirt) (stains) (spots) (and) (grime) • Spot treatment for (pet stains and odors) (insert usage site) • Cleans tough (pet spots) (spots) (and) (pet stains) (stains) (removes) (eliminates) (tough) (dirt) (and) (stains) (pet stains) • Removes dirt, dust, and common allergens (Cockroach, Dust mite and Pet dander)_from (insert usage site) • Cleans everyday (pet) messes • Fast and effective cleaning • Low-Streak -or- Low-Residue -or- Low-Film -or-No-Film -or- Clear-Drying -or-Fast drying] [Formula] [for] [Shiny -or-Multiple Surfaces] • A new technology that is [gentle] [mild] enough to use around your family...on the surfaces they touch the most • Contains no [artificial] [fragrances] [or] 	<ul style="list-style-type: none"> • No sticky or dulling residue on hard floors • Non-abrasive • Non-corrosive • Packaging made with [x%] recycled -or- recyclable plastic • Pleasant smell • Proof is in the clean • Removes dried on [blood] stains • [Gentle] [mild] enough to use on all kitchen surfaces • [Gentle] [mild] enough to use without gloves • Great for [daycare] [lavatory] [restaurant] [office] [school] use! <p>Does not cause damage to device glass, touchscreen glass or surfaces, keyboards, computer terminals</p> <p>Use to keep (pet cages) (dog crates) (cat crates) (pet areas) healthy</p> <p>Worry free use in (kennels) (litter box) (pet areas)</p> <p>Worry Free Use On Toys</p> <ul style="list-style-type: none"> • [Controls] [prevents] [stops] the growth of odor causing bacteria in sponges • Deodorizes sponges • For a cleaner, fresher [bathroom] [kitchen] [home] [house] • [Gentle] [mild] enough to use around [children] [kids] [babies] [your family] [food] [pets] [dogs] [cats] • Great for cleaning [all around] [the] [house] [home] [kitchen] • Great for cleaning just spray [and] [wipe] [walk away] [no rinsing -or- wiping [is] necessary] <p>Spray on pet chew toys, no rinse required</p> <p>No worries about pet licking after cleaning</p> <p>Worry Free Use in Nursery</p> <ul style="list-style-type: none"> • Easy, Effective
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<p>[dyes]</p> <ul style="list-style-type: none"> • Contains no [artificial] [fragrances] [or] [dyes] • [Contains] no [harsh] [harmful] [lingering] [cleaning] chemicals • No Fragrance added formula does not require rinsing • Leaves no [harmful] [chemical] residue • Safe for surfaces that water won't harm • No [mixing] [or] [diluting] [labor] required • Use on hard to reach areas [like nooks and crannies] [shadows] • Use this product in [use sites] 	<ul style="list-style-type: none"> • Frequent Use Formula • For use in whole space [disinfection] on hard non-porous surfaces • Great [suitable] for frequent use • Leaves [room] surfaces disinfected • Makes whole room disinfecting easier on hard non-porous surfaces • No [mixing] [or] [diluting] [labor] required • Use on hard to reach areas [like nooks and crannies] [shadows] • Use this product in [use sites] • Reaches [cracks][, crevices][and shadows]
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<p>Claims:</p> <ul style="list-style-type: none"> • HEAVY DUTY ODOR ELIMINATOR • Fragrance free • Contains no heavy metal, optical brighteners or dyes • Deodorizes [-and/or- disinfects -or- helps deodorize] • Deodorizer [for institutional use] • Deodorizes food odors [like garlic and onion] [left behind on kitchen surfaces] [after cooking] • Eliminates mold odors] • Eliminates odors caused by bacteria [and non-fresh foods] • Eliminates -or- reduces [kitchen] odors [in the trash can -or recycling bin odors -or- smells] [caused by bacteria] • Eliminates pet odors caused by bacteria • Eliminates tough odors • Kills odor-causing bacteria in the kitchen -or- bathroom • Kills odor-causing bacteria • Kills -or- eliminates bacteria that cause [bad] odors • Odor eliminator • Removes -or- eliminates odors • Strong cat odors 	<p>Deodorizations by air claims:</p> <ul style="list-style-type: none"> • Air odor (eliminator) (deodorizer) (fighter) • Controls odors in the air • Controls (the toughest) (tough) (kitchen) (and) (bathroom) (pet) odors (in the air) • Deodorizes (the air) with a (new) (fresh) (pleasant) (clean) fragrance • Eliminates (pet) (food) (bad) odors (in the air) • Fights odors in the air • Gets rid of odors in the air • It's ok to spray (to deodorize) (eliminate odors) (make your home smell fresh and clean) • Leaves your home smelling clean and fresh • Leaves your home (air) smelling clean (and fresh) • Leaves a fresh clean scent • Long lasting freshness • (Now) Freshens (deodorizes) (the air) • (Now) Freshens (deodorizes) (the air) and kills (odor) bacteria on surfaces • Odor (fighter) (eliminator) (elimination) (for the air) • Perfect for eliminating your toughest
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<p>Strong pet odors</p> <ul style="list-style-type: none"> • [This effective product] eliminates odors at their source. [Does not just mask odors.] • Deodorizes areas that are hard to keep fresh smelling • Use to control odors animal kennels • Use to control odors barn stalls. • Eliminates urine and other strong pet odors{cat} {dog} • Eliminates pet odors • Pet waste odors • Cat Urine • Fecal Odors • Eliminates strong ammonia odors • Eliminates strong sulfur odors • Heavy duty odor eliminator removes strong, deep set pet odors • Helps prevent the build-up of odors by killing odor-causing bacteria [on hard, pre-cleaned, non-porous, non-food contact surfaces] • Gets rid of odors by killing the [bacteria] [that cause them] • Eliminates [removes] odors [caused by] [bacteria] • Controls odors caused by [bacteria] 	<p>odors (in the air)</p> <ul style="list-style-type: none"> • Deodorizes by killing bacteria that cause odor[s] • Deodorizes by killing odor-causing [bacteria] at their source • Does not encapsulate odors • Removes odors through [oxidation] [of] [breaking down] [organic and inorganic] [substances] • Breaks down odor causing bacteria through oxidation
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Allergen Removal:

To [clean and] reduce specified allergens: [Set trigger to SPRAY.] Spray, [wait 1 minute], and wipe excess. [Rinse.] Allow to air dry. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel.]

Allergens:

- Cockroach matter -or- particles
- Dust mite matter -or- particles
- Pet dander -or- dog and cat dander

Claims:

- Reduces dust mite matter -or- particles, cockroach matter -or particles, and pet dander allergens
- Reduces Allergens[!]
- Removes Allergens

- Removes allergen from your home
- Cockroach matter -or- particles
- Dust mite matter -or- particles
- Pet dander -or- dog and cat dander
- Reduces allergy-causing particles, such as pet dander, and dust mite matter

Disinfectant Claims:

- | | |
|--|--|
| <ul style="list-style-type: none"> • Antibacterial [spray] [action] [formula] • Disinfectant • Disinfectant [for institutional use] • Disinfects & [and] Deodorizes • Disinfects by killing microorganisms on hard, nonporous surface such as stainless steel, chrome, plastic, glazed ceramic, and mirrors. • Disinfects as it Cleans • Disinfecting spray • Disinfect[s] • Disinfects [to kill the germs] • Easily disinfect -or- Ready-to-use spray [to easily disinfect] • Effectively eliminates (99.999% of) [pathogens] [bacteria] from hard, non-porous surfaces • Effective [alternative] broad-spectrum surface disinfectant • For [hospital] [commercial] [industrial] [&] [institutional] use • For Healthcare Facility use • For Hospital use • disinfects all pre-cleaned, hard, non porous room surfaces • Hard[, nonporous] surface disinfectant • Intended for use in all medical, healthcare, semi-critical care, and long-term care environments • Hospital disinfectant • easy -or- safe on [hard] [common] surfaces -or- [insert use site -or- use surface from this label] • Disinfect. Carry On. • [disinfecting -and/or- deodorizing] [Disinfects -and/or- deodorizes] | <ul style="list-style-type: none"> • kills [99.999% of] bacteria* (list organisms) • Kills and cleans • • Kills bacteria • Kills -and/or- [eliminates] [disinfects] [destroys] [removes] [attacks] [gets rid of] [99.999% of] bacteria -and/or germs on [use sites] Kills Harmful Bacteria • Oxidizing agent to provide disinfection • Ready to use disinfectant cleaner • Reaches into every nook, crevice, and corner that disinfecting sprays [and wipes] can't • Simply clean and disinfect when the disinfection directions for use are followed • Touch up cleaning/disinfection • easy on surfaces • easy to use around patient[s] [areas] • easy enough for everyday use • Two in one, no sacrifice on cleaning and disinfecting • Two in one, cleaning and disinfecting [99.999% of] bacteria - or- Disinfects [washable] kitchen surfaces including killing [99.999% of] bacterial,] • Use in places you are concerned about bacteria - and/or- germs • Use -or- cleans and disinfects on healthcare surfaces • Versatile cleaner disinfectant • Kill[s] -and/or- eliminate[s] -and/or- disinfect[s] - and/or- destroy[s] - - |
|--|--|

Anytime -or- Daily -or- Every <ul style="list-style-type: none"> • For use in CURIS® [System] fogger • For use in room fogging equipment [instrument(s)] [device(s)] [fogger(s)] [system(s)] • Ready-to-Use [formula] [No mixing required] • Go [Goes] above, beyond, under, and around disinfecting sprays and wipes • No wipe, No rinse[, Dry Mist][, Micron Mist] • Whole [complete] Room Disinfection [Disinfecting] System on hard non-porous surfaces • Bleach [Chlorine] [Bleach and Chlorine] [Alcohol] free formula [technology] [disinfection] [disinfecting] [disinfectant] 	and/or- attack[s] -and/or- get[s] rid of [99.999% of] [the] bacteria -and/or- [other] and/or- bacteria from label [commonly found in - or- on[insert use site -or- use surface from this label] <ul style="list-style-type: none"> • Kills pathogenic bacteria • CURoxide™ meets EPA standards for healthcare [hospital] disinfectant • Disinfects hard pre-cleaned, non-porous [non-food] [contact] surfaces [located]in: [use sites] • For [hospital] [healthcare] [medical] [semi-critical care] [long term care] environments as a disinfectant • Treats, does not cover up [no residue] [no need to rinse after use] as a disinfectant
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<p>Specific Disinfecting Claims:</p> <p>Kills [eliminates] (99.999% of) Pseudomonas aeruginosa [Pseudomonas] bacteria</p> <p>Kills [eliminates] (99.999% of) Staphylococcus aureus [Staphylococcus] [Staph] bacteria</p> <p>Kills [eliminates] (99.999% of) Pseudomonas aeruginosa [Pseudomonas] bacteria</p> <p>Kills [eliminates] (99.999% of) Staphylococcus aureus [Staphylococcus] [Staph] bacteria</p> <p>Kills [eliminates] (99.999% of) Staphylococcus aureus [Staphylococcus] [Staph] bacteria</p> <p>EPA registered disinfectant [disinfecting] fogging [solution] [formula] [product] for whole [complete] room surface disinfection [disinfecting] on hard non-porous surfaces</p> <p>Whole space disinfection for enclosed spaces on hard non-porous surfaces</p> <p>An effective disinfectant [solution] [formula] [product] for use in healthcare facilities</p> <p>An effective disinfectant [solution] [formula] [product] for use in healthcare facilities for whole [complete] room surface disinfection [disinfecting] on hard non-porous surfaces</p> <p>An effective disinfectant [solution] [formula] [product] for use in healthcare facilities</p> <p>An effective disinfectant [solution] [formula] [product] for use in [hospital(s)] [healthcare] [medical] [semi-critical care] [long term care] environments for whole [complete] room surface disinfection [disinfecting] on hard non-porous surfaces</p> <p>Effective against bacteria</p>	
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AREAS OF USE INCLUDE:

Vehicles, schools & daycare, gyms & locker rooms, sports gear, hospitals, nursing homes, assisted living, long term care, rehab facilities, food transport vehicle, laundry rooms, veterinary, pharmacies, transportation, busses, trains, transit, ambulances, barber shops, laboratories, restaurants, boats, ships, federally inspected meat & poultry processing plants, farms, animal pens and poultry houses, egg processing premises, hatcheries, swine premise sanitation, refrigerated storage units (empty & disconnected), airplanes, trains, trucks, buses & automobiles.

Medical Use Sites for use on hard non-porous surfaces:

Ambulances -or- [Emergency Medical]
Transport Vehicles
Ambulatory Surgical Centers (ASC)
Anesthesia Rooms or Areas
[Assisted Living -or- Full Care] Nursing Homes
Long Term care
Carts
CAT Laboratories]
Central Service Areas
Central Supply Rooms -or- Areas
Critical Care Units -or- CCUs
Dialysis Clinics [Facilities]
Doctors' Offices
Donation Centers [blood] [plasma] [semen] [milk] [apheresis]
Emergency Rooms -or- ERs
EMS
Exam -or- Examination Room[s]
Eye Surgical Centers
Health Care Settings -or- Facilities
Home Health Care Settings
[Hospital] Kitchens (non-food contact surfaces)
Hospices
Hospitals
Intensive Care Units -or- ICU[s] [areas]
Isolation Areas
Laundry Rooms
Laboratories
Long Term Care Facilities [Clinics] [Facilities]
[Medical] Clinics
Medical Facilities
Medical -or- Physician's -or- Doctor's Offices
Newborn -or- Neonatal [Nurseries] [Intensive Care] Units [NICU]
Nursing Homes
Nursing -or- Nurses' Stations

Operating Rooms or ORs
Ophthalmic Offices
Orthopedics
Out-Patient [Surgical Centers (OPSC)] [Clinics] [Facilities]
Patient Areas
Patient Restrooms
Patient Rooms
[Pediatric] Examination Rooms -or- Areas
Pediatric Intensive Care Units [PICU]
Pharmacies
Physical Therapy Rooms -or- Areas
Physicians' Offices
Psychiatric Facilities
Radiology -or- X-Ray Rooms -or- Areas
Recovery Rooms
Rehabilitation Centers
Respiratory Therapy Rooms -or- Areas
Restrooms
Surgery Rooms -or- Operating Rooms -or- ORs
Tissue Banks
Waiting Rooms -or- Waiting Areas
Wound Care Clinics

Medical Use Surfaces:

Hard, Nonporous Surfaces Associated with the
Following:
anesthesia machines
aphaeresis machines
autoclave exteriors
bathroom doorknob
bedpans
bedrails
[bedside] commodes
bedside tables
blood pressure cuffs
blood pressure (BP) monitors]
cabinet handles
call boxes
CAT -or- Computerized Axial
Tomography equipment)
carts
cellular phones
charging stations

closet handles
coated mattresses
coated pillows
[computer] mice
computer tables
cords
counters
[crash] [emergency] carts desktops
diagnostic equipment]
dialysis machines]
docking stations
[exam -or- examination] tables
exterior surfaces of air vents -or- air vent
exteriors
external surfaces of [medical] equipment
-or- [medical] equipment surfaces
isolettes
IV [stands] [pumps] [poles]
large surfaces
loupes
mammography equipment]
[Mayo] [instrument] stands
medication carts
mobile devices
mobile workstations
mouse pads
MRI -or- Magnetic Resonance Imaging
equipment
nurse-call [devices] [buttons] [and
cords]
operating room tables and lights
operator light switches
oxygen hoods
overbed tables
paddles
pagers]
[patient] chairs
patient monitoring equipment]
patient support and delivery equipment]
phlebotomy trays
physical therapy (PT) equipment
portable bathrooms
prescription container exteriors
pulse oximeters

PVC tubing
reception counters -or- desks -or- areas
remote controls
scales
side rails
slit lamps
small surfaces
spine backboards
[external] [surfaces of] ultrasound
transducers [-and/or- probes]]
exterior of pipes
footboards
glucometers]
gurneys
[hard, nonporous] edges of privacy curtains
hard, nonporous hospital
-or- medical surfaces
hard, nonporous surfaces
headboards
[hard, nonporous] high touch surfaces
[hospital -or- patient] bed[s] [springs]
[railings] [frames] [linings]
infant incubators and care cribs
infant warmers
[inner] [inside of] drawers
stethoscopes
stools
stretchers
surfaces in and around toilets in patient
rooms
toilet handholds
toilet[s] [rims -or- seats]
traction devices
walls [around toilet] [in patient rooms]
wash basins
safety rails
Hard non-porous whirlpool surfaces
Wheelchairs

Dental Use Sites:

Dental Offices
Dental Operatories
Examination Rooms Dental -or- Dentists' Offices
Dental Surfaces:

Hard, Nonporous Surfaces Associated with the following:

amalgamators-and/or-dental curing lights
endodontic equipment such as apex locators
pulp testers and motors
dental countertops hard, nonporous dental reception counters -or- desks -or- areas
dental operatory surfaces
light lens covers

Veterinary Use Sites:

Animal [Pet] Housing [Kennels] [Facilities](Pens)
(Cages)
Animal Holding Areas
Animal Life Science Laboratories
[Animal -or- Pet] Grooming Facilities
Animal Transportation Vehicles
Breeding Establishments
Dairy Farms
Equine Farms
Farms
Kennels
Litter Boxes
Livestock -and/or- Swine -and/or- Poultry Facilities
Pet [Areas] [Quarters]
Pet Shops -or- Stores
Pet waters and feeders
Small Animal Facilities
Tack Shops
Veterinary Clinics -or- Facilities
Veterinary [Offices] [Waiting Rooms]
Veterinary -or- Animal Hospitals
Veterinary Examination Rooms
Veterinary X-ray Rooms
Veterinary Operating Rooms
Zoos

Veterinary Use Surfaces:

Hard, Nonporous Surfaces Associated with the following:
animal equipment
automatic feeders
cages
surfaces of fountains
exterior surfaces of watering appliances
feed racks
hard, nonporous veterinary surfaces

pens
reception counters -or- desks -or- areas
research facilities
stalls
troughs
veterinary care surfaces

Food Service Use Sites for non-food contact surfaces:

Banquet Halls
Bars
Cafeterias
Catering Facilities
Commercial -or- Institutional Kitchens
Delis
Fast Food Chains -or- Restaurants
Food Preparation and Processing Areas School Kitchens
Food [Service -or- Processing] Establishments
Food Serving Areas
Vending Machines
Water Coolers
Water fountains
Food Service Surfaces:
Hard, Nonporous Surfaces Associated with the following:
dish racks
drain boards
food cases
food trays
freezer exteriors
hoods
[kitchen] appliance exteriors
microwave exteriors
plastic -or- metal outdoor furniture
refrigerator exteriors
salad bar sneeze guards

Miscellaneous/General Use Sites:

Airplanes [Airports]
Ambulances
Athletic [Recreational] Facilities
Automobiles
Barber Shops
Basements
Bathroom [s]
Bathroom -or- Locker Room

Buildings

Buses

Facilities

Beauty Salons

Bedroom [s]

Blood Banks

Boat interiors

Bowling Alleys

Bus interiors

Butcher Shops

Cafeterias

Camper interiors

Car interiors

Churches

Colleges

Computers

Convenience Stores

Correctional Facilities

[Damp] Storage Areas

Day Care Centers

Den[s]

Dining Room

Dorms

Dormitories

Elevators

Emergency Vehicles

Factories

Fast Food Restaurants

[Food Processing]

[Manufacturing] Plants

Funeral Homes

Gas Stations

Grocery Stores

Gymnasiums -or- Gyms

Garbage] [Waste] Storage Areas

Living Room

Locker Rooms

Lodging Establishment

Lounges

Malls

Manufacturing Plants -or-

Facilities

Markets

Mass Merchandisers, Discount

Retailers
-and/or- General Merchandise
Stores
Mobile Homes
[Mobile labs](#)
Mortuaries
Motels
Motor Home Interiors
Mudrooms
Nurseries
Office[s] [Buildings]
Pet Animal Quarters
Health Club[s] [Facilities]
Home[s]
Home Centers
Hotels
Industrial Facilities
Institutional Kitchens
[Institutional] Laundromats
Institutions
Kennels
Kitchen[s] [Surfaces]
Laboratories
Laundromats
Laundry Room[s]
Pet Areas
Crates
Carries
Pet Bedding
Pet Car Seats
Pet Feeders
Pet Water Dishes
Dog Houses
Dog Runs
Pet Toys
Litter Boxes
Bird Cages
Cage Accessories
[Educational facilities](#)
Feeder & waters
Small animal cages
Pharmacies
Play Areas-or-Rooms
[Police -and/or- Fire] Vehicles

Produce Areas
Public Facilities
Public Restrooms
Recreational Centers -or-
Facilities
Rental Cars
Residential facilities
Rest Stops
Restroom[s] -or- Restroom Areas
Retail Businesses
School Buses
Schools
Shelters
Shipping containers
Ships
Shopping Centers
Shops
Shower Rooms
Sports Arenas -and/or- stadiums
Storage Rooms -or- Areas
Subways
Supermarkets
Tattoo Parlors
Toolsheds
Transportation Terminals
Transportation vehicle
Trains
Trolleys
Universities
Vacation Homes
Warehouse Clubs

Miscellaneous/General Surfaces:

Hard, Nonporous Surfaces

Associated with the following:

cabinet knobs
appliance exteriors
armchairs
[baked] enamel
Bassinets
Bathroom mats
[bathroom] fixtures
[bathroom] [kitchen] faucet[s]
[handles]

[bath]tubs
bed frames
behind and under counters
behind and under sinks
boat interiors
booster chairs
Box Springs
brush handles
burner trays
Cabinets
Car Seats
car interiors
carts
chairs -or- arm chair
[children's] furniture
closets
hampers
coated ceilings
cooler exteriors
counters -or- countertops
cupboards
cribs
crutches
crystal (non-food contact areas)
dashboard
desk[s] [tops]
diaper pails
[dining] [fast food] [kitchen]
[picnic] [play]
[restaurant] [tray] [diaper -or infant]
[changing] [tables] -or- [areas] -
or-[stations]
dining room surfaces -and/or tables-
and/or-fast food restaurant
tables
door[s] [handle[s]] [frames]]
Doorknobs
Drawer pulls
Dressing carts
Elevator buttons
Exercise balls
Exercise bands
exercise [machines]
[equipment]

exhaust fans
exterior -or- external toilet
surfaces
exterior -or- external urinal
surfaces
faucets
[filing] [medicine] cabinets
free weights
freezer exteriors
furniture
garage surfaces
garbage-or-trash cans
glazed ceramic [restroom
surfaces]
glazed [ceramic] tile[s]
glazed porcelain [tiling -or- tile]
grill surfaces
[grocery [store] -or supermarket]
carts
[handles] [child seats]
gymnastic] equipment
Hampers
[hand]railings -or- rails
hard, nonporous floors [around
toilets]
[hard] plastic -or- vinyl
headsets
helmets
high chairs (non-food contact
surfaces)
High touch areas
[kids'] play [structures]
[equipment]
[furniture] [tables]
[kitchen] appliance exteriors
kitchen appliance exterior[s]
[surfaces]
light fixtures -or- switches -or panels
rocking chairs
RV interiors
sealed fiberglass
shelves [and drawers]
shin guards
shoes

shopping carts
shoulder pads
shower[s] [area] [curtains]
[doors] [stalls] [walls]
signs
sink[s] [basins]
seats
sports equipment
stainless steel
stall doors
staplers
steering wheel
stools
stretchers
synthetic marble
tables [tabletops]
[tiled] walls
Tires
[Exterior of toilet [flush]]
[telephone][cabinet]
[dishwasher][door] handles
linoleum
lockers
metal
metal blinds
metal work benches
microwave exterior
office machinery
office -or- bedroom -or- bedside
furniture
patio furniture
pencil sharpeners
pet areas -or- surfaces
[plastic] fly swatters
plastic laundry hampers -or- baskets
plastic patio furniture -or- lawn
chairs
plastic shower curtains
plastic surfaces associated with:
floors,
walls, Mirrors, toilets, urinals, sinks,
shower rooms and locker rooms
Playpens
portable toilet exteriors

range hoods
recycling bins
refrigerator exterior [door handles]
tray tables
tubs
urinals
vanity tops -or- vanities
vehicle interiors
vending machine surfaces
[vinyl] linoleum -or- wallpaper
walkers
walls
wash basins
[washable] kitchen[s] [surfaces]
washers/dryers -or- washing
machine
exteriors]
wastebaskets
weight machines
whirlpool tubs -and/or- Jacuzzis
window [blinds] [shades]
windshields
[wrestling] [exercise] mats
Tools
towel dispensers
toy boxes-or-storage bins
trailers
Exterior of toilet [training] toilets
trash cans -or- compactors
Horticultural and
Botanical Use Sites:
Aeroponic growing facilities
Aquaponic growing facilities
Basement greenhouses
Botanical bio-film [non-public
health bio-film]

**Horticultural and
Botanical Use Sites:**

Aeroponic growing facilities
Aquaponic growing facilities
Basement greenhouses
Botanical bio-film [non-public
health bio-film]

Botanical facilities
Commercial greenhouses
Customer/public areas
Employee areas including break
Floral shops
Garden centers
Hardscape storage areas
Herbal dispensaries
Hobby greenhouses
Horticultural bio-film
Horticultural facilities
Hydroponic growing facilities
Landscape nurseries
Lawn and garden shops
Plant growing chambers
Plant growing facilities
Plant growing rooms
Plant holding areas
Plant nurseries
Plant transport vehicles
Plant storage areas
Plant supply storage areas
Plant warehouses
Vendor delivery areas

Horticultural and

Botanical Use Surfaces:

Hard, Nonporous Surfaces
Associated
with the following:
Cash registers
Compost bins
Compost equipment
Containers, buckets, pots, trays
Display coolers
Display shelving
Germination stations
Grafting stations
Greenhouse equipment
Greenhouse films
Greenhouse irrigation systems
Greenhouse tools, scissors, and
measuring cups
Greenhouse ventilation/air

handling systems
Grow tents and nets
Horticultural air exchangers
Office equipment and/or
machinery
Plant benches
Plant blankets
Plant carts, wagons,
wheelbarrows
Plant coolers
Plant display racks
Plant grow shelves
Plant shelters
Plant transport racks
Pollination trays
Produce/flower testers
Propagation trays
Row covers
Shade materials
Supply cupboards
Supply shelving
Transplant equipment
[washable][surfaces]-and/or
general merchandise

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage:

Store in original closed container in a cool, dry, place away from direct sunlight and heat. Do not freeze. Keep away from small children and pets.

Pesticide Disposal:

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Offer empty container for recycling. If recycling is not available, discard container in trash.

If product is leaking or spill should occur, please dilute with water and dry with absorbent material. Discard excess or used (product) solution in drain with running water.

NOTICE: Seller expressly warrants that the product conforms to its chemical description. There are no other warranties associated with the sale of this product.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. Contact a Poison Control Center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, call the National Pesticides Information Center at 1-800-858-7378.

You may also contact the Poison Control Center at 1-800-222-1222 for emergency medical treatment information.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Avoid breathing vapor or spray mist. Do not get in eyes, skin, or on clothing. Wear goggles, safety glasses or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment

The following PPE is recommended:

- Protective eyewear such as goggles or face shield, or safety glasses
- Require at least half-face piece respirator (and appropriate eye protection) with either 3M 6003 or 6006 (organic vapor/acid gas or multigas cartridge in

combination with particulate filter (i.e., 5N11 or 5P71), if hydrogen peroxide levels
≥1 ppm for re-entry the treated room

-Gloves, long sleeves, and long pants



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[Package Insert or additional label language for
CURoxide™
EPA Reg. No. 93324-1]

CURoxide™





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1. GENERAL

CURoxide™ has been registered with CURIS® System, in accordance with Federal Regulations for the specific uses described on the product label, package insert and CURIS® Fogger User Manual. CURoxide™ is for use as a hospital disinfectant on hard non-porous, pre-cleaned surfaces by personnel properly trained in the use, operation and safety of the CURIS® System.

2. USER SAFETY REQUIREMENTS AND PRECAUTIONS

Refer to the product label for user safety requirements and PPE.

- a) Keep out of reach of children.
- b) Carefully read and understand all warnings, cautions, and safety instructions before use.
- c) Avoid contact with eyes or clothing. Seek medical attention if contact with eyes.
- d) Use only as directed. Follow guidelines set forth in this manual when using the CURIS® Fogger.
- e) Use only CURIS® System approved chemicals.
- f) Do not enter the room when the CURIS® Fogger is in use. Use a Drager, Portasens, or similar monitor, equipped with a hydrogen peroxide sensor to monitor the minimum effective concentration, as well as re-entry levels within the enclosure are less than or equal to a 1 ppm level (≤ 1.0 PPM TWA 8 hr.) prior to reentry into the enclosure by trained personnel
- g) Do NOT inhale mist; avoid contact with skin or eyes.
- h) Use proper protection when working with chemicals. Personal Protection Equipment (PPE), which includes gloves and eye protection is recommended.
- i) Do not alter or modify your CURIS® Fogger. Use only replacement parts authorized by CURIS® System. Repairs must be made by CURIS® System or the warranty is void.
- j) Cover smoke detectors, fire alarms and sensing systems before fogging.
- k) Do not stack CURIS® Foggers. Tipping may occur and cause chemical spillage. Damage may occur to the unit and surrounding areas.
- l) Do not allow the CURIS® Fogger or associated components to get wet. Electric shock, injury and damage may occur.
- m) If the electric power cord is frayed, cut or damaged in any way, do not use. Replace with CURIS® System replacement cord. Always plug CURIS® Fogger power cord into GFCI outlet.
- n) Do not stop, block or prevent air from entering the Cooling Air Inlets or Cooling Fan Exhaust.
- o) Protect fogger from severe impact or shock.



- p) Unplug CURIS® Fogger before moving.

3. DISINFECTION MANAGEMENT PLAN (DMP)

3.1 General Guidance.

A Disinfection Management Plan (DMP) should be developed and used by employees for each location prior to treatment. Manage and address all factors to ensure an effective and successful disinfection. The guidance should include subjects such as:

- a) Inspect the structure or area to determine its suitability for disinfection (size, non-porous surfaces, pre-cleaned, etc.).
- b) Seal the room to be treated adequately to ensure that DMHP (Dry Mist Hydrogen Peroxide) levels outside the room are kept at acceptable levels and that there is adequate coverage of product within the room. Periodically monitor any occupied adjacent rooms and/or buildings to ensure safety.
- c) Prior to each disinfection, review any existing DMP, SDS, User Manuals and other relevant safety procedures with appropriate employees.
- d) Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be in and around the area during application and aeration.
- e) Consult with company officials to develop an appropriate monitoring plan that will confirm that nearby workers and bystanders are not exposed to levels above the allowed limits during application. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.
- f) Confirm the placement of placards to secure entrance into any area under disinfection.
- g) Confirm the required safety equipment is in place and the necessary manpower is available to complete disinfection.

These factors must be considered in putting a DMP together. It is important to note that some plans will be more comprehensive than others. All plans should reflect the experience and expertise of the applicator and circumstances at and around the structure and/or area. A DMP must be developed for each treated site. In the event of an emergency application, a generic DMP may be used and updated after disinfection.

3.2 Personnel

In addition to the DMP, personnel must read the entire label, this package insert, and the CURIS® Fogger User Manual. Personnel must follow all directions carefully. Personnel must be adequately trained and certified by CURIS® System or its



authorized distributor or reseller on the hazards and label directions for CURoxide™, the use and operation of the CURIS® System, monitoring procedures and, when appropriate, disinfection validation procedures. If the trained personnel have any questions about the development of a DMP, contact CURIS® System for further assistance.

3.3 Worksite requirements

- a) Review existing product label DMP, company protocols, equipment manuals prior to treatment.
- b) Confirm in writing that all personnel in and around the area to be fogged have been notified prior to application of the disinfectant. Consider using a checklist that each employee initials indicating that they have been notified.
- c) Instruct all disinfection personnel about the hazards that may be encountered, the selection of PPE, and the use of any hydrogen peroxide detection equipment.
- d) Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.
- e) Instruct all personnel on how to report any accident or incidents related to disinfectant exposure.
- f) Establish a meeting area for all personnel in case of emergency.
- g) Confirm that all applicators have been trained in the use of the CURIS® System and safety equipment.
- h) Develop a Worker Health and Safety Plan as required by OSHA for applicators. The owner and operators of the facility being treated should have a Worker Health and Safety Plan as required by OSHA developed for their employees located within close proximity of the application process.

3.4 Worksite Monitoring

- a) For safety requirement, monitoring of CURoxide™ DMHP concentrations must be conducted immediately adjacent to the fogged space to prevent excessive exposure and to determine if exposure occurs. A device similar to the Draeger X-am 5100 OR PortaSens II may be used.
- b) When monitoring for leaks, confirm that there is no DMHP present above the 0.2-ppm level. Subsequent leak monitoring is not routinely required. However, spot checks should be made, especially if the area significantly changes.
- c) Monitoring must be conducted during aeration and corrective action taken if H₂O₂ levels exceed the allowed levels in an area where bystanders or nearby residents may be exposed. Ensure that adjacent areas, where levels have exceeded 1 ppm, are evacuated of general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue



monitoring the area until levels are below <1 ppm DMHP. The treated room and adjacent areas must remain unoccupied until DMHP levels are below 1ppm.

4. CURIS® SYSTEM USER INSTRUCTIONS

4.1 Area Preparation

- a) CURIS® Fogger use does not replace the requirement for manual room cleaning. For use in pre-cleaned spaces and pre-cleaned equipment. Remove any visible gross contamination and bio-films from surfaces and equipment before fogging. Wash soiled surfaces using a cloth, sponge, wipe or appropriate cleaning device to ensure visible soils are removed. All the surfaces within the treatment area must be dry to the touch prior to initiating DMHP application.
- b) Review existing product label DMP, company protocols, equipment manuals prior to treatment.
- c) Area Inspection:
 - a) Take measurements of the room for programming of the CURIS® Fogger or entry into CSDM. Document length, width, and height in feet.
 - b) Locate and identify smoke detectors, air conditioning supply and returns, any gaps or holes, vents, etc., that require sealing. Note position and types of equipment and furniture.
- c) Take note of proximity to staff and general public.
- d) Expose - Open all drawers, cabinets, and doors to areas if they are to be included in the service.
- e) Environmental Conditions
 1. Temperature – Temperature is not critical to treatment parameters however, 23 C +/- 3 C is optimal.
 2. Humidity - Target relative humidity is below 50% relative humidity (RH). Dehumidification by use of a dehumidifier may be used if the space to be treated is above 50% relative humidity.
- f) Validation
 1. Chemical indicators may be used to indicate consistent area coverage.
 2. Biological Indicators may be used to validate product performance.
 3. Document service or utilize CSDM for automatic capturing of information.
- g) Securing -Seal all openings to prevent DMHP leaks during servicing. Cover smoke detectors, air conditions supply and returns, gaps, holes, vents, etc. Place Warning placards on all entry/exit points. Remove all plants and animals.



4.2 System Operation and Process

Refer to the CURIS® Fogger User Manual for specific instructions on programming the CURIS® Fogger.

3 Phases of The CURIS® Fogger

1. **FOGGING PHASE** – This is the initial fogging phase responsible for the initial injection of product into the targeted space. The Cubic Feet of the space to be treated is entered into the CURIS® FOGGER and the programming calculates the Fog time necessary according to the volume of the area to be treated. The CURoxide™ product is then dispensed into the space to reach targeted concentrations of aerosolized hydrogen peroxide (AHP) at a use rate of .3ml/cf. A constant red light will illuminate to provide a visual indication of the Fogging Phase.
2. **PULSE PHASE** – This is the contact time of the fog (the fog dwell time). In this phase, additional product is injected into the treatment space while cycling on and off to maintain the optimal levels of aerosolized hydrogen peroxide according to the area's volume. The Pulse time will automatically default to 20 minutes and allow for increased time if desired. The constant red light will remain on during this phase.
3. **DISSIPATION PHASE** – This is after the completion of the full fog cycle (FOG PHASE AND THE PULSE PHASE) a blinking red light will indicate the aeration cycle has begun and a secondary dissipation unit such as an air scrubber or dehumidifier may be activated. Either natural dissipation or incorporating the use of an air scrubber/dehumidifier is acceptable.

4.3 Protocol

- a) Position the CURIS® Fogger on a level surface approximately two foot from the wall and facing towards the center of the area to be disinfected.
- b) Position the misting nozzle as desired. Point the nozzle vertical for high ceilings, horizontal for low ceilings or crawl spaces, or any point in between as needed. Do not aim nozzle at objects, walls or ceilings within 6 feet.



- c) Plug the CURIS® Fogger into an AC outlet. If an air scrubber or similar is to be used, plug it into the CURIS® Fogger A/C Power Outlet and set the power switch to on (failure to do this will not allow automatic activation). The CURIS® Fogger will supply power automatically, by system logic during the Dissipation phase.
- d) Enter area size into the CURIS® Fogger (The CURIS® Decon app may be used to accomplish the following procedure wirelessly. Contact CURIS® System for more information). There are two manual methods of entry for area size:
 - 1. Measurements: If the room is a rectangular layout, enter length, width and height in feet. The CURIS® Fogger system logic will automatically calculate cubic feet and FOG Time.
 - 2. CUBIC FEET: For room layouts of irregular shape or using multiple foggers to decrease FOG Time (see User Manual Operational Guidelines page 8). Enter CUBIC FEET, and the CURIS® Fogger system logic will automatically calculate FOG Time.
- e) PULSE Time can be adjusted to increase contact time above 20 minutes if desired. Refer to Operational Guidelines in User Manual.
- f) The Data Entry Panel will prompt to confirm that adequate chemical exists for the selected CUBIC FEET of the area to be treated. Refer to the CURIS® Fogger User Manual to for detailed instructions.
- g) Press and hold Start/Stop Button for 3 seconds until Status Light Bar begins blinking red. Leave the room within 60 seconds. After 60 seconds, the Status Light Bar will illuminate red and fogging will commence.
- h) Seal the area and post the "DO NOT ENTER, DISINFECTION IN PROCESS" placard on the outside of the entry points. Do not re-occupy the area until the disinfection process (FOG, PULSE and DISSIPATION) has been completed and the DMHP levels are less than 1 ppm. Other indications of the completion of the disinfection process will be the illumination of the Status Light Bar as green. Use a Draeger X-am 5100 H2O2 gas sensor or similar device to determine that H2O2 levels are below 1ppm, the level required for safe re-occupation as per OSHA guidelines.
- i) If an air scrubber or similar is being utilized, it will automatically begin to operate at the end of the PULSE Time and will continue to operate until either the unit is unplugged or power is removed from the CURIS® Fogger.
- j) When it is safe to enter the room, unplug and remove the fogger, remove all covers from HVAC, smoke detectors, fire alarms and door sweeps.



4.4 Re-entry

RE-ENTRY TO SEALED ROOM

Re-entry to a sealed room by a trained applicator is allowed under the following circumstances:

- a) Only enter the room to perform a planned task, e.g. to retrieve equipment, open windows, augment aeration process etc. and leave the room in the shortest time possible.
- b) Always wear wrap around style goggles to protect against irritation of eyes.
- c) Determine hydrogen peroxide levels prior to room entry using a handheld hydrogen peroxide detector (example: Draeger or ATS PortaSens II).
- d) Hydrogen Peroxide levels between 1 and 10 ppm require at least half-face piece respirator (and appropriate eye protection) with either 3M 6003 or 6006 (organic vapor/acid gas or multigas) cartridge in combination with particulate filter (i.e. 5N11 or 5P71). *
- e) Using a full-face piece respirator (when quantitatively fit tested) with either cartridge
 - a. Mentioned in 5.4.2.c gives an Assigned Protection factor of 50 for use up to 50ppm of Hydrogen Peroxide. *

*3M Technical Bulletin #185. Otherwise, do not re-enter the treated room until exposure levels are below 1 ppm H₂O₂.

EARLY ROOM RE-ENTRY

In case of an emergency and/or unknown levels of DMHP that may exceed applicable exposure limits within the treated room requires a Self-Contained Breathing Apparatus or an airline respirator. When entering into an area with the CURIS® Fogger running, always work under the direct supervision of a trained applicator wearing appropriate PPE.

RELEASING TREATED SEALED ROOM FOR RETURN TO SERVICE

- a) The treated room can be released for general public use after DMHP levels are determined to be at or below 1 ppm. The hydrogen peroxide levels may be verified by the use of a hydrogen peroxide meter such as Draeger or ATS PortaSens II.
- b) Once DMHP levels are determined to be below 1 ppm, applicators may re-enter the treated room and remove any sealing materials including any covered fire



alarms, smoke detectors. Disconnect and remove the CURIS® Fogger from the treated sealed room.

- c) Turn on ventilation systems including HVAC.
- d) Remove placards and release the treated room for normal operation.

4.5 Maintenance

Refer to the CURIS® Fogger User Manual for instructions regarding unit maintenance and troubleshooting guidance.

5. STORAGE AND SHIPPING

- a) Storage: Store in a safe, dry location. Do not place anything on top of the device. Store in an upright position. Keep the refill door closed.
- b) Do not allow CURoxide™ to be stored in the CURIS® Fogger for longer than one year.
- c) Disposal: Electrical and electronic devices may not be disposed of with domestic waste. This product is in accordance with the law "waste electrical and electronic equipment" (WEEE).